

C. Remarks

The claims are 1-15, with claims 1, 10 and 15 being in independent form. Claims 1-9 and 15 have been withdrawn as being directed to non-elected subject matter. No new matter has been added. Favorable reconsideration of the present claims is respectfully requested.

Claim 10 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for use of the phrase "for which a taste is detected in water." Applicants respectfully traverse the rejection.

Applicants submit that one of ordinary skill in the art reading the specification and claims of the subject application would readily understand the meaning of the phrase. Specifically, it relates to the concentration at which the taste of the active is detected. Further, the meaning is explained at page 6, line 13 through page 7, line 5 of the subject specification as filed. In view of the foregoing, it is believed that the phrase "for which a taste is detected in water" in claim 10 is not indefinite and withdrawal of the rejection under § 112, second paragraph, is respectfully requested.

Claims 10-14 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,817,323 (Hutchison), as well as being allegedly unpatentable over U.S. Patent No. 5,635,200 (Douglas) in view of Hutchison and U.S. Patent No. 4,532,126 (Ebert) in view of Hutchison. Applicants respectfully traverse the rejections.

Prior to addressing the grounds of rejection, Applicants wish to briefly review certain features and advantages of the presently claimed invention.

The present invention discloses a chewable soft capsule comprising an outer envelope encapsulating a dispersion of crystals or granules of active substance in a

lipophilic vehicle. The lipophilic vehicle has a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water, and the crystals or granules are coated by a coating for taste masking purposes. The lipophilic fill provides an "over-coating" of the taste masked active, such that when the lipophilic fill is released from the capsule in the mouth, a thin lipophilic layer surrounds the active coated particles and provides additional isolation of the taste buds. Page 5, lines 15-18. This improves the taste-masking function of the capsule leading to a better product, specifically for unpleasant tasting active ingredients.

In the present claims, the lipophilic vehicle is chosen specifically to have a limited solubilization power for the active and/or for at least one of the components of the taste mask coating. Page 6, lines 10-12. The acceptable degree of solubilization of the drug or active substance is a function of drug loading and taste of the active. Page 5, lines 19-20. In the case of an active with a very unpleasant taste, the lipophilic vehicle will be selected so as not to solubilize or minimize the solubilization of the active and the coating components. Page 6, lines 16-20. As disclosed in Example 4 and shown in Table 14 on page 42 of the subject specification as filed, where four lipophilic vehicles having different solubilization values for the active are tested for taste-masking ability, the resulting data is directly related to those values.

Hutchison discloses compositions for use in the shell of a soft gelatin capsule. Specifically, it teaches compositions including gelatin and a plasticizer, as well as the optional use of a hydrophobic solvent or a coated particle. However, as acknowledged by the Examiner, Hutchison fails to teach a lipophilic vehicle having a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected, nor does it even suggest the importance of the relationship between the

solubilizing power of the lipophilic vehicle and the concentration of the active substance at which taste is detected. In contrast, the present invention teaches that by specifically combining coated particles with a lipophilic vehicle tailored to that coating, as well as the active, improved taste-masking and stability of the coating may be achieved. This is not merely an obvious routine or manipulative experimentation during capsule formation, as alleged by the Examiner, but, as set forth in the subject specification, *inter alia*, in Example 4, superior results are achieved by tailoring the lipophilic vehicle according to the solubility of the active and coating therein. Therefore, since Hutchison fails to disclose or suggest the limitation regarding the solubilization of the lipophilic vehicle, and clearly fails to appreciate the benefits achieved thereby, Applicants submit that it does not render the present invention obvious and respectfully request withdrawal of the § 103 rejection.

Douglas discloses compositions for masking the bitter taste of ranitidine, including coating ranitidine with a lipid. As acknowledged by the Examiner, Douglas fails to teach capsule shell components in the amounts claimed in the present invention. Ebert discloses a chewable soft gelatin capsule, which upon formation may be simultaneously filled with a fill material. As acknowledged by the Examiner, Ebert fails to teach coated crystals or granules of active agent in a lipophilic vehicle.

While the Examiner cites Hutchison in combination with each of Douglas and Ebert, it is clear that all three references suffer from the same basic deficiency, namely the failure to teach or to suggest a lipophilic vehicle having a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected, as claimed in the present invention.

Therefore, for at least the reasons set forth above, Hutchison, Douglas and Ebert, in any permissible combination, fail to disclose or suggest key elements of the

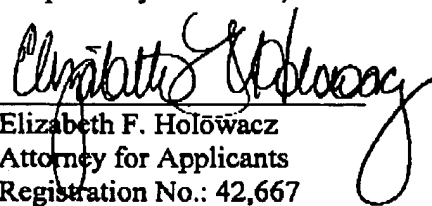
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claimed invention. Accordingly, Applicants respectfully request withdrawal of the § 103 rejections.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,


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